



**POLITICAL  
INTELLIGENCE**

# European Health Data Space

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## Introduction

On May 3, the European Commission [published](#) its plans for the European Health Data Space (EHDS), a new framework designed to make it easier for individuals, doctors, researchers, and regulators to access and use information about the health of millions of citizens across the European Union. The network, which will require actions at the EU and national levels, aims to create a genuine single market for electronic health record systems--a key pillar of the bloc's European Health Union-- following the EU's high data protection standards.

In a statement to mark the launch of the plan, Stella Kyriakides, Commissioner for Health and Food Safety, said, "The European Health Data Space is a fundamental game changer for the digital transformation of healthcare in the EU. It places the citizens at its centre, empowering them with full control over their data to obtain better healthcare across the EU. This data, accessed under strong safeguards for security and privacy, will also be a treasure trove for scientists, researchers, innovators and policymakers working on the next life-saving treatment. The EU is taking a truly historic step forward towards digital healthcare in the EU."

This Dods EU Political Intelligence report provides a brief outline of the Commission's EHDS plan and compiles some of the key political and stakeholder views that were set out ahead of its publication.

### The EHDS proposal in brief

The EHDS plan has three key [objectives](#):

1. To give individuals better digital access to their personal health data and to support free movement by having that data follow them across the Union
2. To promote the data economy by fostering a single market for digital health services and products
3. To set up strict rules for the use of an individual's non-identifiable health data for research, innovation, policy-making and regulatory activities.

In its proposal, the Commission explains that while the EU health sector is rich in data, it is poor in making it work for people and science. For this reason, the EHDS aims to harness the wealth of health data across the Union to help prevent, diagnose and treat diseases, support research, improve healthcare delivery, and speed up the development of new medical products and treatments – all while adhering to its strong principles of data privacy and control. The Commission says the COVID-19 pandemic, in particular, showed the importance of digital services in the health domain and how up-to-date, reliable health data is key for providing an efficient public health response to a crisis.

In terms of data protection, the EHDS will build on horizontal frameworks such as the General Data Protection Regulation (GDPR), the proposed Data Governance Act, the draft Data Act, and the NIS Directive. To address the special sensitivity of health data the EHDS proposal includes more specific requirements, such as access control, and plans to adopt a proposal for a Cyber Resilience Act in 2022 to set out the cybersecurity requirements for digital products and ancillary services.

The Commission's EHDS plan covers the use of primary data, secondary data, common governance, and synergies with other health policy priorities. In terms of primary data, the EHDS aims to enable the millions of citizens of the EU to access their own health data and make it

available to a health professional of their choice, including when abroad and in other languages, and also enable health professionals to update those records.

The plan envisages integrating three main product markets for the primary use of health data: electronic health records, other health and medical software products such as medical imaging software, and wellness apps. Mandatory requirements for interoperability, security, safety and privacy will be introduced. The plan includes pilot projects for viewing the mobile devices in other EU countries, and transitional periods for member states to adapt to obligations required, such as the registration of health data, and making data available in the European format. To wit, all Member States will be required to participate in MyHealth@EU, a cross-border digital infrastructure for the exchange of health data for healthcare delivery.

In terms of secondary use of data, the EHDS aims to set out a common EU framework allowing for use of anonymized health data of EU citizens for research, innovation in public health, policymaking, regulatory activities, and personalised medicine. It will draw on the creation of a new and decentralised EU infrastructure for secondary use of health data called HealthData@EU which will connect access bodies in all EU member states.

This infrastructure, which will be piloted in a EU4Health project starting in 2022, includes plans for permits governing the access to the anonymized health data and how it can be used, and closed secure environments with clear standards for cyber security. The data will not be allowed to be used to make decisions that could be detrimental to individuals, to increase insurance premiums, to market health products toward health professionals or patients or design harmful products or services. The Commission hopes the EHDS will help support some of its other health initiatives, such as Europe's Beating Cancer Plan, facilitate research under the Horizon Europe Cancer Mission, and help meet the aims of both the Pharmaceutical Strategy for Europe and the mandate of the European Health Emergency Preparedness and Response Authority (HERA). The system will also enable researchers and innovators from third countries to access data for secondary use under the same conditions and requirements as those inside the EU. The proposal will also aim to reinforce the governance of health data at the national and EU level. It will build on the current cooperation for primary use of data, within the eHealth Network, which helped to build, in a record time, two EU-wide infrastructures during the COVID-19 pandemic: the EU Digital COVID Certificate and contact tracing and warning apps. This will include the creation of a new European Health Data Space Board to oversee the system, chaired by the Commission and staffed by representatives of digital health authorities and health data access bodies from the member states.

In terms of the next steps, the publication of the Commission's EHDS plan paves the way for the Council and the European Parliament to consider the proposal according to the usual EU legislative process. In the European Parliament, the file is likely to be handled by the Committee on the Environment, Public Health and Food Safety (ENVI) and the Committee on Civil Liberties, Justice, and Home Affairs (LIBE).

## Political and stakeholder views

### Council of the European Union

At the time of writing, the Council had not adopted a specific position on the Commission's EHDS proposal. However, the French Presidency of the Council of the EU has sought to set the groundwork for developments with parallels to the EHDS plan, including approval of [European principles for ethics in digital health](#) at the conference on "Citizenship, Ethics and Health Data" on 2 February. These incorporate four ethical dimensions: placing digital health within a framework

of humanist values, enabling people to manage their health data digitally, developing inclusive digital health, and implementing eco-friendly digital health. The Presidency has said it hopes the principles “will be a tool for improving mutual understanding to facilitate discussions on the future European regulation on the European Health Data Space”.

The potential benefits of the EHDS were also noted in a recent meeting of the [Health Council](#) during a debate on combatting rare diseases. During the debate, ministers noted the importance of cooperation among member states and medical establishments on rare diseases and pointed to the role that the planned EHDS could play as “access to high-quality health data within a safe framework could also help make new, safer, personalised treatment accessible sooner”.

### European Parliament

The European Parliament has also yet to comment on the EHDS proposal, although it touched on the issue of health data in a [non-legislative resolution](#) on the pharmaceutical strategy adopted in late November 2021. The resolution, drafted by Spanish centre-right MEP Dolors Montserrat, set out the Parliament’s views on aspects of the Commission’s upcoming EHDS proposal and addressed the general question of how to ensure the protection of this data. While it welcomed the Commission’s ambition to “leverage the full potential of real-world data and access to rare therapies and to ensure fair, transparent and non-discriminatory access to data throughout Europe”, it added that there must be “full and harmonised application of the GDPR”. It said the protection of personal data would be central to the success of the project, and to enable and promote trust and data innovation in digital health. It also said that health data should not be commercialised and the sale of such data to the pharmaceutical industry, health insurance providers, technology companies and employers should be prohibited.

Montserrat’s report also called for the promotion of primary and secondary use of aggregated health data and called upon the Commission to “support measures favouring open science in order to accelerate the sharing of data and research results within the scientific community in Europe and beyond”. The resolution called for the Commission to “develop European federated data networks aiming to contribute to optimal research, development and healthcare delivery” and for data to be used to help ensure the “full potential of AI in the field of healthcare”. It also noted that the creation of large, high-quality health data sets would aid the research and treatment of pathologies, especially rare diseases and paediatric conditions.

### Stakeholders

While reaction to the Commission’s announcement has been muted, several stakeholders have set out their views on the EHDS plans in recent months.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) put forward a [detailed set of recommendations](#) for the EHDS ahead of its publication. It said the objective should be to enable the connection and flow of data across the EU to empower more effective and efficient research and development of new treatments and diagnostics, as well as better planning and delivery of patient-centred care through personalised medicine. The federation has called for increased awareness and cooperation among all stakeholders and to develop a shared understanding of the relevant requirements in digital health, a common data model to allow data to be accessed, pooled, compared and used, while ensuring privacy, and for privacy by design principles to apply. It has also stressed the need for legal clarity noting that “regulatory and legal uncertainty over the rules for pharmaceutical companies accessing, processing and sharing data would impact on the ability to innovate and respond to public health needs”.

The Director General of Digital Europe, Cecilia Bonefeld-Dahl laid out her [expectations](#) for the proposal noting that it should reaffirm the “EU’s coordinating role for the digital transformation of health systems”. She also pointed to the need to ensure that the proposal does not cause fragmentation and burdens in compliance by guaranteeing that there is no legal uncertainty with the scope of the proposal and its interaction with other data legislation including the GDPR, the Data Governance Act, the Data Act and the AI Act. Ensuring there are enough financial resources behind the proposal was also a concern of hers. Digital Europe also published a [position paper last year](#) entitled A digital health decade: from ambition to action. Following the publication of the Commission documents, Digital Europe expressed its [support](#) for the proposal while noting that many of its concrete aspects will need to be implemented later on which could result in fragmentation, as was seen with the implementation of the GDPR.

In mid-April, EURORDIS, which represents rare disease patients in Europe, also [pointed](#) to the importance of sharing data in the fight against rare disease. They argued that “health data, coupled with active patient engagement and connected clinical and research networks, is the recipe to transform care delivery and drive research and innovation” and called for the Commission proposal to be built on “a strong system of data governance and rules for data exchange, data quality, and strong infrastructure and interoperability”. Calling for a harmonised system of how to treat data, EURORDIS noted that the new rules “must prevent data from being used to enable discrimination for insurance, loans and work”. They also pointed to the need for rare diseases patients to travel to another country to receive treatment and thus noted that “safe and timely sharing of their health data across countries is key”.

Medtech Europe, which represents the medical technology industries, produced a [position paper](#) in June 2021 calling on the EU to take on a coordinating role to realise the full potential of health data, noting that “aligning inconsistent national strategies through an EU-wide governance framework will enable the harnessing of health data in a resource- and cost-effective way”. The paper stressed the need to find the right balance between data protection and innovation to “boost the competitiveness of the European medical technology industry and establish Europe as the premier location for healthcare research and development”. Medtech Europe called for clear rules for processing health data by medical technology companies, legal certainty on the interplay between different regulations including the GDPR and the Medical Devices and In-Vitro Diagnostics Regulations, harmonised guidelines on anonymisation and pseudonymisation, as well as the possibility to transfer health data within and outside the European Economic Area.

The European Data Protection Supervisor (EDPS) has not commented on the actual proposal, but did put forward an [opinion](#) on the original Commission Communication. The EDPS indicated its strong support for the objectives of promoting health-data exchange and fostering medical research but stressed the necessity for data protection safeguards to be defined at the outset of the creation of the EHDS. Noting the sensitivity of the health data in the planned EHDS, it said “the boundaries of what constitutes a lawful processing, and a compatible further processing of the data must be crystal-clear for all the stakeholders involved. Therefore, the transparency and the public availability of the information relating to the processing on the EHDS will be key to enhance public trust in the EHDS.”

The BioMed Alliance Taskforce on Health Data Sharing, in close cooperation with the European Association of Urology (EAU) and the European Organisation for Research and Treatment of Cancer published a [joint statement](#) on the EHDS plans in December 2021 noting that facilitating health data sharing could ensure “numerous benefits for health research, policy making and healthcare”. They called for the proposal to “align different legislative approaches with a clear and enabling EU legal framework which defines secondary use for all EU member states, enables



research, and gives legal clarity on the framework which applies". They also asked whether a European Health data protection seal or certification would be useful and noted the need for targets and benchmarks for data interoperability.

Reacting to the publication of the plan, COCIR, the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries, [welcomed](#) the proposal as a potential catalyst for unlocking the potential of health data in the EU with its emphasis on data access and interoperability. The association, however, warned of potential hurdles to watch out for, namely the potential overlaps with the Data Act, the interplay with GDPR, and conformity requirements for electronic health records.

The European Cancer Organisation also [welcomed](#) the proposal, noting that "the cancer community has long seen the need for a serious initiative to achieve the full potential of data cooperation across borders for the improvement of research, care and health policy."

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